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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/628,324      | 07/29/2003  | Joh-E Ikeda          | 2003-0980           | 6188             |
| 513             | 7590        | 08/08/2006           |                     | EXAMINER         |
|                 |             |                      |                     | AEDER, SEAN E    |
|                 |             |                      | ART UNIT            | PAPER NUMBER     |
|                 |             |                      |                     | 1642             |

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | Application No.                  | Applicant(s)     |
|------------------------------|----------------------------------|------------------|
|                              | 10/628,324                       | IKEDA ET AL.     |
|                              | Examiner<br>Sean E. Aeder, Ph.D. | Art Unit<br>1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 30 May 2006.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 17-33 is/are pending in the application.  
4a) Of the above claim(s) 17-22 and 24-33 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 23 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

***Detailed Action***

The response filed on 6/20/06 to the restriction requirement of 5/30/06 has been received. Applicant has elected Group II and SEQ ID NO:3 for examination. Because Applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)). Further, it is noted that SEQ ID NO:3 represents a distinct invention and not a species, as indicated in the response filed 6/20/06.

Claims 17-33 are pending.

Claims 17-22 and 24-33 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claim 23 is currently under consideration.

***Objections***

Claim 23 is objected to for being dependant upon an unelected claim.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because claim 23, as written, does not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed

products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claim is inclusive of a genus of antibodies that bind a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof*. However, the written description in this case only sets forth antibodies that specifically bind polypeptides consisting of SEQ ID NO:3. The specification does not disclose any other antibodies that bind a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof* as broadly encompassed in the claims.

The specification teaches the polypeptide sequence consisting of SEQ ID NO:3 and antibodies that would specifically bind said sequence. The specification does not teach polypeptide sequences flanking SEQ ID NO:3. Therefore, the specification does not teach sequences to which an antibody would specifically bind outside of SEQ ID NO:3 in a polypeptide comprising SEQ ID NO:3. Further, the specification does not teach every polypeptide that comprises the amino acid of SEQ ID NO:3 with specific deletions, substitutions, and/or additions of amino acids. Therefore, the specification does not teach sequences to which antibodies specific for every possible variant of SEQ ID NO:3 would bind. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at \*9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative

number of antibodies that encompass the genus of antibodies that bind a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof* nor does it provide a description of structural features that are common to antibodies that bind a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof*. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of SEQ ID NO:3 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of antibodies that bind a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof* or the detailed structure of every possible sequence *comprising* SEQ ID NO:3 and *variants and fragments thereof*, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of

isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an antibodies that selectively bind a polypeptide consisting of SEQ ID NO:3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Korneluk et al (WO 97/26331; 7/97).

Claim 23 is drawn to an antibody against a polypeptide *comprising* SEQ ID NO:3 and *variants and fragments thereof*.

Korneluk et al teaches a sequence, AAW20032 (SEQ ID NO:22 and 24), which shares 99% similarity to instant SEQ ID NO:3 (see attached sequence comparison). Korneluk et al further teaches nucleic acids encoding polypeptide fragments of AAW20032 (see page 43, in particular). Korneluk et al further teaches monoclonal and polyclonal antibodies that specifically bind polypeptides comprising AAW20032 (SEQ ID NO:22 and 24) (see pages 21-22, in particular). Korneluk et al further teaches said antibodies are generated by the entire AAW20032 (SEQ ID NO:22 and 24) sequence and by polypeptide fragments of AAW20032 encoded by specific nucleic acids (see last paragraph on page 21 and the last paragraph on page 50, in particular). Because of the high degree of homology between AAW20032 (SEQ ID NO:22 and 24) and instant SEQ ID NO:1, one of skill in the art would recognize antibodies taught by Korneluk et al would bind polypeptides comprising instant SEQ ID NO:3.

### ***Summary***

No claim is allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300..

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER

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